

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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EMELY MONTERO,

Plaintiff,

-against-

TEVA PHARMACEUTICALS USA INC., and  
ORTHO MCNEIL JANSSEN  
PHARMACEUTICALS, INC.,

Defendants.  
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**ORDER GRANTING MOTION  
TO DISMISS**

19 Civ. 9304 (AKH)

ALVIN K. HELLERSTEIN, U.S.D.J.:

Plaintiff Emely Montero brings claims for negligence, strict products liability, breach of express warranty, breach of implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud against two pharmaceutical companies in connection with injuries allegedly stemming from her use of Tri-Lo Sprintec. Defendant Ortho McNeil Janssen Pharmaceuticals, Inc. (“Janssen”) moves to dismiss for failure to state a claim. Janssen’s motion is granted.

Janssen does not manufacture, distribute, or sell Tri-Lo Sprintec. Instead, as Plaintiff acknowledges, Janssen makes Ortho Tri-Cyclen Lo. Tri-Lo Sprintec, the product that plaintiff used, is the generic version of Ortho Tri-Cyclen Lo, Janssen’s product.<sup>1</sup> Plaintiff

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<sup>1</sup> Although the complaint suggests at certain points that Janssen only manufactures Ortho Tri-Cyclen Lo and not Tri-Lo Sprintec, it states elsewhere that Janssen does indeed manufacture Tri-Lo Sprintec. *Compare* Compl. ¶¶ 20-21 (“Defendant [Teva Pharmaceuticals USA, Inc.], was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Tri-Lo Sprintec . . . . Tri-Lo Sprintec is the generic version of Ortho McNeil Janssen’s oral contraceptive, Ortho Tri-Cyclen® Lo.”), *with* Compl. ¶ 27 (“Upon information and belief, and at all relevant times, Defendant [Janssen] was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Tri-Lo Sprintec for use as an [sic] birth control and irregular menstrual cycles.”). Plaintiff’s memorandum in opposition to Janssen’s motion to dismiss continues this contradiction. ECF No. 25, at 12 (“Plaintiff does not state that [Janssen] manufactured a generic drug . . . .”). The Court takes judicial notice of records from the FDA, cited by Janssen, which make clear that neither Janssen nor any Janssen-affiliated company has ever been approved to sell Tri-Lo Sprintec. *See Gale v. Smith & Nephew, Inc.*, 989


attempts to proceed on a theory of “innovator liability,” arguing that the manufacturer of a name-brand drug can be liable for injuries caused by the generic version, particularly where the generic drug’s manufacturer uses the warning label from the brand-name product. Courts applying New York law have consistently rejected this theory. *See Rosser v. Sanofi-Aventis*, No. 17-cv-2396, 2018 WL 4080351, at \*4 (S.D.N.Y. Aug. 26, 2018); *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 720-22 (S.D.N.Y. 2017); *Goldych v. Eli Lilly & Co.*, No. 04-cv-1477, 2006 WL 2038436, at \*6 (N.D.N.Y. July 19, 2006); *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993 (Sup. Ct. N.Y. Cty. Oct. 8, 2013). Plaintiff has not sufficiently alleged that Janssen owed her a duty or that Janssen was the cause of her injuries.

Plaintiff will not be granted leave to amend because amendment would be futile. *Ellis v. Chao*, 336 F.3d 114, 127 (2d Cir. 2003). Plaintiff has not shown that she can put forth any facts plausibly alleging that Janssen caused her alleged injuries.

For the foregoing reasons, Janssen’s motion to dismiss is granted with prejudice. The Clerk of Court shall terminate Janssen as a party.

SO ORDERED.

Dated: New York, New York  
December 17, 2019

  
ALVIN K. HELLERSTEIN  
United States District Judge

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F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (taking judicial notice of approval posted to FDA website). To the extent Plaintiff is attempting to allege that Janssen directly participated in the manufacture of Tri-Lo Sprintec, not just a precursor to Tri-Lo Sprintec, I need not accept “factual assertions that are contradicted by the complaint itself, by documents upon which the pleadings rely, or by facts of which the court may take judicial notice.” *Perry v. NYSARC, Inc.*, 424 F. App’x. 23, 25 (2d Cir. 2011).